K082377

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510(k) Summary

Date of Summary prepared: January 21, 2005

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Submitted Device:

Generic name: Transcutaneous Electrical Nerve Stimulator (TENS)

Trade name: Tenscare itouch

Common name: TENS device

Classification name: Stimulator, Nerve, Transcutaneous, for Pain Relief - **GZJ; 21 CFR 882.5890.**

Device Classification: Class **II**

Predicate Devices: EasyMed TENS Unit TN-28C (K040253)
Gemore GM300T (K032720) (http://www.gemore.com.tw/)

The class of the predicate Devices:
Class II

Device Description: A portable TENS device for pain relief.

Features:

- Innovative design
- Large LCD display
- Dual output isolated channels
- 2 AA Alkaline Batteries
- Adjustable frequency, pulse width, and timing parameters
- 9 different modes
- Timer option
- Doctor lock/unlock facility
- Open circuit detectors
- Non-volatile

The intended use of the device:

TENS stands for Transcutaneous Electrical Nerve Stimulation. The itouch TENS system is indicated for:

- Symptomatic relief and management of chronic, intractable pain.
- Adjunctive treatment for post-surgical and post-trauma acute pain.

The intended use and indications for use of the new device are very similar to that of the predicate devices.

Technological Comparison:

1. The marketed device EasyMed TN-28C (K040253) is a digital TENS unit which has been well exploited the digital technology, supplying the user with full ranges of parameters, traditional TENS functions, and non-traditional new functions to be selected.

2. The designed circuitry of new device itouch is very similar to the marketed device TN-28C, they are of similar circuit diagrams and similar working principle; The main difference between the two devices is that TN-28C is not a constant current TENS device while itouch is a constant current device.

3. Both itouch and TN-28C (K040253) are passed the same tests of applicable recognized international consensus standards.

4. The marketed device Gemore GM300T (K032720) is a TENS device with constant current output. The specification of GM300T is very similar with that of itouch.

5. The new device itouch is of the same range of parameters as those of marketed devices.

6. Itouch was designed and added the constant current feature based on the design of TN-28C (K040253). The introduction of marketed device Gemore GM300T (K032720) is for the purpose of comparison of the feature of constant current.

7. The accessories of the new device itouch are similar to those of the marketed devices.

Labelling Comparison: The Labelling is substantially equivalent to that of the predicate devices.

Safety information:

Design to comply with relevant safety applicable recognized consensus standards; the output energy is well controlled in the safety and effectiveness ranges specified by relevant FDA guidance's. Testing has been carried out in very detailed and strictly. Test results, Risk Analysis, and FMEA analysis show that the new unit itouch is safe with no any hazard.

itouch has been marketed in Europe. During this period a review of Customer Complaints, Returned Product and the results of Post Market Feedback, has demonstrated that the product has performed

as Intended, to its' Specified Requirements.

The new device itouch is of the feature of constant current. But this feature is only applied in the range of load from 500Ω to 1500Ω, the current is being get down and tends to zero when the load is being get far from this range, this character makes the device safe reliably.

Submitted times: It is the first submission to FDA for this new device

Conclusions: The itouch TENS unit is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

Important remark: There are two models for Tenscare itouch TENS devices: "Easy" and "Plus". Because all functions of "Easy" can be covered by "Plus" (see instruction manual in Section V), we do not discuss "Easy" model in this submission and consider it as no significant change.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Tenscare Ltd
% Mr. Anthony Jankel
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United Kingdom

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Re: K082377
Trade Name: Tenscare TENS Model itouch
Regulation Number: 21 CFR 882.5890
Regulation Names: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: December 12, 2008
Received: December 12, 2008

Dear Mr. Jankel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name : Tenscare TENS Model itouch

Indications for Use

TENS stands for Transcutaneous Electrical Nerve Stimulation.

This TENS system is indicated for:

- Symptomatic relief and management of chronic, intractable pain.
- Adjunctive treatment for post-surgical and post-trauma acute pain.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082377